Office of New Drug Quality Assessment
Program Description

Goals: The purpose of this rotation is to familiarize the student with the role of the Food and Drug Administration (FDA) in the regulation and review of drug products. Activities will focus on review process as it relates to drug development, drug product quality and safety, as well as offer exposure to the impact of pharmaceutical science on the multidisciplinary review process.

I. Learning Objectives: Upon completion of this rotation the student will be able to:

A. Describe the development of a new drug from laboratory to commercial distribution of the product and the FDA's role in that process.
B. Become familiar with terminology used for current manufacturing practices for drug products.
C. Observe the multidisciplinary review process involved with the review of new drugs at the FDA.
D. Distinguish between the three phases of clinical trials in the drug development process.
E. Discuss ways the FDA makes new drugs available to patients prior to approval.
F. Outline the regulatory submissions necessary for the various stages of drug development, ranging from first-in-human studies to commercialization.
G. Become familiar with the laws, regulations, and guidance documents governing drugs.
H. Actively participate in internal scientific discussions of various aspects of drug development and pharmaceutical manufacturing.

II. Student Requirements: The student will be exposed to a variety of issues regarding all aspects of pharmaceuticals and the pharmaceutical industry. The program will focus on familiarizing the student with the overall review process for all stages of drug development. To meet these objectives the student will be expected to:

A. Refrain from sharing confidential information obtained during any part of the rotation.
B. Conduct a project assigned by preceptor. Project will be related to manufacturing sciences. Topics may include, but are not limited to, drug product quality, drug recalls, raw material attributes, excipient interactions, and manufacturing processes.
C. Attend various internal seminars and trainings to further exposure to the review process.
D. Attend multidisciplinary meetings regarding multiple issues involved with drug development and review.
E. Attend student rotations within the Office of the Commissioner and the Center for Drug Evaluation and Research, when applicable.
F. Fulfill required hours.